

MRID No. 442377-01

DATA EVALUATION RECORD
§ 71-4 -- AVIAN REPRODUCTION TEST

1. CHEMICAL: Metaldehyde PC Code No.: 053001

2. TEST MATERIAL: Metaldehyde technical Purity: 99%

3. CITATION:

Authors: J.B. Beavers, S. Trumbull, J. Grimes, and
M. Jaber

Title: A Pilot Reproduction Study with
Metaldehyde in the Mallard

Study Completion Date: April 8, 1994

Laboratory: Wildlife International Ltd., Easton, MD

Sponsor: Lonza Inc., Fair Lawn, NJ

Laboratory Report ID: 289-105

MRID No.: 442377-01

DP Barcode: D238845

4. REVIEWED BY: Max Feken, M.S., Environmental Toxicologist,
Golder Associates Inc.

Signature:

Date:

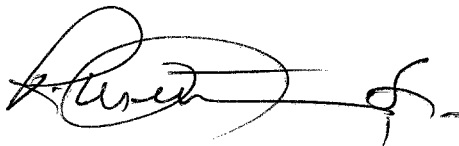
APPROVED BY: Pim Kosalwat, Ph.D, Senior Scientist,
Golder Associates Inc.

Signature:

Date:

5. APPROVED BY:

Signature:



Date:

5/9/98

6. STUDY PARAMETERS:

Scientific Name of Test Organism: *Anas platyrhynchos*

Age of Test Organisms at Test Initiation: 31 weeks

Definitive Study Duration: 6 weeks

7. CONCLUSIONS: This study was conducted as a pilot study to determine general toxic effects of metaldehyde on the mallard. This study is scientifically sound but does not meet the guideline requirements for an avian reproduction study (Subdivision E, 71-4(b)). Based on treatment related mortalities and reductions in egg production at the 1000 and 2000 ppm treatment levels, the NOEC was 300 ppm.



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Results Synopsis

Most sensitive endpoints: Eggs laid

NOEC: 300 ppm

LOEC: 1000 ppm

8. ADEQUACY OF THE STUDY:

A. Classification: Supplemental

B. Rationale: This study does not meet the guideline requirements for an avian reproduction study (Subdivision E, 71-4(b)).

C. Repairability: No.

9. GUIDELINE DEVIATIONS: This study was a pilot study and was not designed to meet Guideline No. 71-4. The deviations from the guidelines are noted as follows:

1. The test was conducted for 6 weeks with no pre-egg laying phase.
2. Only five pens with one male and one female per treatment level were used; at least twelve pens per treatment are required for northern bobwhite in groups of two.
3. The number of eggs laid was the only reproductive parameter measured.
4. Treatment related mortalities occurred at the two highest concentration groups (1000 and 2000 ppm).

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
<u>Species</u> A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>), or an upland game species, preferably the northern bobwhite (<i>Colinus virginianus</i>)	Mallard (<i>Anas platyrhynchos</i>)
<u>Age at beginning of test</u> Birds should be approaching their first breeding season.	31 weeks old; birds were approaching their first breeding season.
<u>Supplier</u> All birds should be from the same source.	Whistling Wings, Inc. Hanover, Illinois
Were birds pen-reared?	Yes
Were birds phenotypically indistinguishable from wild birds?	Yes
<u>Health observation period</u> 2 to 6 weeks.	10 weeks
Were birds healthy and without excessive mortality prior to the test?	Yes

B. Test System

Guideline Criteria	Reported Information
Were pens for adult birds of adequate size and designed to conform to good husbandry practices?	Yes
Were pens for chicks of adequate size and designed to conform to good husbandry practices?	Yes

Guideline Criteria	Reported Information
Were pens constructed of a nonbinding material such as galvanized or stainless steel?	Yes
Was adequate ventilation provided?	Yes
<u>Temperature</u> Approx. 21°C (70°F)	Mean: 20.1°C SD: 1.4°C
<u>Relative humidity</u> Approx. 55%	Mean: 55% SD: 16%
<u>Lighting</u> <u>First 8 weeks:</u> 7 h per day. <u>Thereafter:</u> 16-17 h per day. At least 6 footcandles at bird level.	17 h per day Mean illumination: 534 lux.
<u>Diet</u> A commercial breeder feed (or its equivalent) that is appropriate for the test species.	27% protein minimum 2.5% fat minimum 5% fiber maximum 5% limestone
<u>Preparation of test diet</u> A premix containing the test substance should be mechanically mixed with basal diet. If an evaporative vehicle is used, it must be completely evaporated prior to feeding.	Test diets were prepared by mixing the test substance into a premix which was used for weekly preparation of the final diet.
Was the premix stored under conditions which maintain stability?	Premix was frozen.
Was the diet analyzed to verify homogeneity and stability of the test substance?	Yes
<u>Replenishment of feed</u>	Diets were prepared weekly. Feed and water were provided <i>ad libitum</i> .

C. Test Design

Guideline Criteria	Reported Information
<u>Nominal concentrations</u> At least two concentrations other than the control are required; three or more are strongly recommended. The highest test concentrations should show a significant effect or be at or above the maximum field residue level.	Nominal concentrations: Control, 300, 1000, and 2000 ppm Max. residue level: Not reported
<u>Control</u> Vehicle control.	Negative control
<u>Vehicle</u> Corn oil or other appropriate vehicle.	No vehicle was used
<u>Vehicle amount (% of diet by weight)</u> Not more than 2%.	N/A
<u>Number of birds per pen</u> One male and 1 female per pen is strongly recommended. For quail, 1 male and 2 females may be acceptable. For ducks, 2 males and 5 females may be acceptable.	1 male and 1 female per pen
<u>Number of pens per group</u> At least 5 replicate pens are required for mallards housed in groups of 7. For other arrangements, at least 12 pens are required, but considerably more may be needed if birds are kept in pairs.	5 pens per group
<u>Pre-laying exposure duration</u> At least 10 weeks prior to the onset of egg-laying.	No pre-laying exposure period.
<u>Exposure duration with egg-laying</u> At least 10 weeks.	6 weeks

Guideline Criteria	Reported Information
<u>Withdrawal period</u> If reduced reproduction is evident, a withdrawal period of up to 3 weeks may be added to the test phase.	N/A

D. Egg Collection and Incubation

Guideline Criteria	Reported Information
Were eggs collected daily?	Yes
<u>Egg storage temperature</u> Approximately 16°C (61°F)	Eggs were not stored.
<u>Egg storage humidity</u> Approximately 65%	N/A
Were eggs set weekly?	Eggs were not set.
Were eggs candled for cracks prior to being set for incubation on Day 0?	No
<u>Candling for fertility</u> Quail: approx. Day 11 Ducks: approx. Day 14	N/A
<u>Transfer of eggs to hatcher</u> Bobwhite: Day 21 Mallard: Day 23	N/A
<u>Hatching temperature</u> 39°C (102°F) is recommended	N/A
<u>Hatching humidity</u> 70% is recommended	N/A
<u>Day after egg set that chicks were removed and counted</u> Bobwhite: Day 24 Mallard: Day 27	N/A

E. Eggshell Thickness Measurement

Guideline Criteria	Reported Information
<u>Collection Schedule</u> At least once every two weeks (Week 1, 3, 5, 7 and 9).	Eggs were not collected for egg shell thickness
Were shells opened, washed, and air dry for at least 48 hours before measuring?	N/A
<u>Measurement</u> 3-4 measurements per eggs to the nearest 0.01 mm.	N/A

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Did diet analysis verify the concentrations of test material?	Yes
Did diet analysis show that the test substance was stable and homogeneous?	Yes
Were body weights of adults reported for test initiation and biweekly up to week 8 or the onset of egg laying?	Body weights were measured at test initiation, and weeks 2, 4, and 6.
Was average food consumption of adults reported at least biweekly?	Yes

Guideline Criteria	Reported Information
Reproductive Endpoints The following endpoints should be reported: <ul style="list-style-type: none"> • Eggs laid • Eggs cracked • Eggs set • Viable embryos • Live 3-week embryos • Normal hatchlings • 14-day-old survivors • Weights of 14-day-old survivors • Egg shell thickness • Total food consumption • Initial and final body weights, by sex 	Only number eggs laid, food consumption and adult body weights were measured.
Were data reported by pen for all endpoints?	Yes

Significant Results: All birds at the highest treatment concentration (2000 ppm) had died by the end of the test (6 weeks). Treatment related mortalities (3 birds) were also observed at the 1000 ppm test concentration. Symptoms of toxicity included reduced reaction to external stimuli, lacrimation, lethargy, and trembling. There were no overt signs of toxicity in birds at the 300 ppm treatment concentration. There were no treatment related reductions in adult body weights or feed consumption when compared to the control. While egg production at the 300 ppm test concentration was comparable to the control, no eggs were laid at the 1000 and 2000 ppm treatment groups.

13. **VERIFIED STATISTICAL RESULTS:**

Means of Endpoints

Endpoint	Control	300 ppm	1000 ppm
Eggs laid (EL)	7 (12)	17 (18)	0 (0)
Mean food consumption (FOOD)	179 (80)	166 (40)	159 (18)

Endpoint	Control	300 ppm	1000 ppm
Final weight of males (POSTM)	1239 (136)	1241 (64)	1369 (171)
Final weight of females (POSTF)	1086 (48)	1145 (187)	1151 (154)

Statistically Significant Endpoints: There were no statistically significant reductions.

14. **REVIEWER'S COMMENTS:** While the data in this pilot study was too sparse and variable to produce any statistically differences, from visual inspection it appears that there were no treatment related effects at the lowest concentration (300 ppm) tested. However, until a definitive test is performed, this is not a scientifically defensible conclusion.

This study was conducted as a pilot study to determine the general toxicity of metaldehyde technical to the mallard ducks approaching their first breeding season. Although it does not meet the guideline requirements for an avian reproduction study, the results can be used as supplemental data for assessing toxicity of metaldehyde. Based on treatment related mortalities and reductions in egg production at 1000 and 2000 ppm, the NOEC and LOEC for metaldehyde was 300 and 1000 ppm, respectively.